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12 162 732 06/11/95 H01 EN

EXAMINER
JORDAN, K

ART UNIT PAPER NUMBER

5

12P01 0912
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1205

DATE MAILED:

09/12/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 1 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-41 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-41 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1205

Claims 1-41 are presented for examination.

Claims 28-41 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited ^{to} contraception and ameliorating incidents of breakthrough bleeding and amenorrhea. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 28 and 35 are drawn to "fertility control" which is broader than the specific type of fertility control of contraception which is disclosed by the specification. Claims drawn to "contraception" would obviate the rejection. Likewise, claims 28 and 35 are drawn to "ameliorating uterine bleeding control problems" but the specification only discloses reducing incidents of breakthrough bleeding and withdrawal amenorrhea as bleeding control problems. The remaining claims are unenabled to the extent that they depend on the rejected base claims.

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Claims 1-24 and 26-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 1 is indefinite due to the word "also" in the third to the last line of the claim. It is unclear why the word is necessary after the word "optionally". It is suggested that the word "to" be substituted for "also". Claim 3 is indefinite as the word "progestin" has no preceding article which suggests that the compound intended is the specific compound Progestin rather than the general class of progestins. Claim 11 is similarly indefinite as there is no article preceding either "estrogen" or "progestin". Furthermore, claim 11 is indefinite as there is no antecedent basis in claim 1 for the term "progestin". Claim 12 is indefinite as it is a duplicate of claim 9 and fails to further limit the subject matter of a preceding claim. Claims 14-15 and

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19 are indefinite as they lack antecedent basis for the word "progestin". Claim 21 is indefinite due to the phrase "at least about 20" when the claim later stipulates that 21 tablets are necessary to be effective. The phrase "at least about 20" is confusing in view of the later stipulation. Claim 23 is indefinite as there is a missing bracket corresponding to the bracket before the phrase "the progestin" in the second the last line of the claim. Thus, it is unclear whether the phrase "the progestin is...mifepristone" is included or not. Claims 26 and 27 are indefinite as they are composition claims but improperly refer back to method claim 19. Claims 26 and 27 are also indefinite in the amounts recited for ethinyl estradiol and norethindrone acetate because the amounts do not fall within the ranges of claim 25 (from which claims 26 and 27 are presumed to depend). The remaining claim are indefinite to the extent that they depend upon the rejected base claims.

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Claims 28-41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 54-67 of copending application Serial No. 08/115,008. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-41 of this application conflict with claims 1-41 of application serial number 08/462,705. 37 C.F.R. § 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See M.P.E.P. § 822.

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The remaining references listed on the enclosed PTO-1449 are cited to show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kimberly Jordan whose telephone number is (703) 308-4611. The examiner can normally be reached on ? from ? to ?.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ?, can be reached on (703) ?. The fax phone numbers for this Group are (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or 305-3592.



**KIMBERLY JORDAN
PRIMARY EXAMINER
GROUP 1200**

JORDAN; aco
September 8, 1995